

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,

Petitioner,

v.

EYE THERAPIES, LLC,

Patent Owner.

Case IPR2022-00142
U.S. Patent No. 8,293,742

DECLARATION OF ROBERT O. WILLIAMS, III, Ph.D.

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I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

1. I, Robert O. Williams, III, Ph.D., submit this declaration at the request of Patent Owner Eye Therapies, LLC (“Eye Therapies” or “the Patent Owner”) as an expert in the design and evaluation of drug products. I understand that this declaration is being submitted in support of the Patent Owner’s Response in connection with IPR2022-00142. My qualifications in these areas, as well as other areas, are established below and by my curriculum vitae, which is attached as Appendix A.

2. I am currently the Johnson & Johnson Centennial Chair and Professor in the Division of Molecular Pharmaceutics and Drug Delivery at the University of Texas at Austin College of Pharmacy in Austin, Texas, where I have been teaching and conducting research since 1995. I am also the Division Head of Molecular Pharmaceutics and Drug Delivery.

3. I received a B.S. degree in biology from Texas A&M University in 1979, a B.S. degree in pharmacy from The University of Texas at Austin in 1981, and a Ph.D. degree in pharmaceutics from The University of Texas at Austin in 1986. I am a licensed pharmacist.

4. I have extensive experience and expertise in pharmaceutical formulation and the use of excipients in formulating various types of drug dosage

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forms. I am an expert in the field of pharmaceutical development, and I have worked almost exclusively in the field of pharmaceutical development since 1986. While I am not an FDA expert, I work with team members who are FDA experts and have knowledge of relevant FDA regulations governing drug products. Based on my experience, I am also generally familiar with FDA guidance and testing requirements.

5. Prior to becoming a professor, I worked in the pharmaceutical industry for several companies including Rhone-Poulenc Rorer Pharmaceuticals, Duramed Pharmaceuticals, and Eli Lilly and Company. Additionally, from 1996 to 2007, I was co-founder and President of PharmaForm, a contract pharmaceutical laboratory, and from 2007 to mid-2010, I was a director of Akela Pharma. I was the Chief Scientist and co-founder of Enavail from 2009 to 2013, a particle engineering contract services company founded based on intellectual property on which I am a co-inventor. I am a scientific consultant to TFF Pharmaceuticals, Inc, a company founded based on intellectual property on which I am a co-inventor. Accordingly, I have relevant industry experience in addition to my academic qualifications.

6. My current research focuses on the development, formulation, optimization, and delivery of drugs by a variety of technologies. I have extensive research experience and have authored numerous publications in this area.

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